July 2002

Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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The Montana Board of Pharmacy is proposing several new rules, rule additions, and rule changes. PROPOSED wording follows, with public hearing in July. We invite your comments.

Institutional Pharmacy Rules

8.40.702 Definitions

(1) **Facility** means an ambulatory surgical facility, a hospital and/or long-term care facility, or a home infusion facility.

8.40.702 (2) Deleted

8.40.702 (3) Deleted

8.40.702 (4) Deleted

8.40.702 (5) (family planning centers) remains unchanged but should be moved to another section

(2) **Institutional Pharmacy** means that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed to other health care professionals for administration to patients within or outside the facility, and pharmaceutical care is provided; and which is registered with the Montana State Board of Pharmacy.

(3) **Biological safety cabinet** means a contained unit suitable for the preparation of low to moderate risk agents and where there is a need for protection of the product, personnel and environment according to National Sanitation Foundation Standard 49.

(4) **Class 100 environment** means an atmospheric environment which contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E.

(5) **Clean Room** means a room in which the concentration of airborne particles is controlled.

(6) **Cytotoxic** means a pharmaceutical agent capable of killing living cells.

(7) **Drug Order** means a written order issued by an authorized practitioner, or a verbal order promptly reduced to writing and later signed by an authorized practitioner, for the compounding and dispensing of a drug or device to be administered to patients within the facility.

(8) **Drug Room** means a secure, lockable temperature-controlled location within a facility that does not have an institutional pharmacy and which contains drugs and devices for administration to patients within the facility pursuant to a valid drug order.

(9) **Emergency Drug Cart (Crash Cart)** means a secure, lockable cart containing drugs and devices necessary to meet the immediate therapeutic needs of inpatients or outpatients and which cannot be gotten from any other authorized source in sufficient time to prevent risk of harm or death to patients.

(10) **Emergency kits** are sealed kits containing those drugs which may be required to meet the immediate therapeutic needs of patients within an institution not having an in-house pharmacy, and which would not be available from any other authorized source in sufficient time to prevent risk of harm or death to patients.

(11) **Floor Stock** means prescription drugs not labeled for a specific patient which are maintained at a nursing station or other hospital department other than the pharmacy, and which are administered to patients within the facility pursuant to a valid drug order. Floor stock shall be maintained in a secure manner pursuant to written policies and procedures, which shall include but not be limited to automated dispensing devices.

(12) **Formulary** means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.

(13) **Home infusion facility** means a facility where parenteral solutions are compounded and distributed to outpatients pursuant to a valid prescription or drug order.

(14) **Long term care facility** means a nursing or retirement home or other facility which provides extended health care to resident patients.

(15) **Night cabinet** means a secure, locked cabinet or other enclosure located outside the pharmacy, containing drugs which authorized personnel may access in the absence of a pharmacist.

(16) **Parenteral** means a sterile preparation of drugs for injection through one or more layers of skin.

(17) **Sterile pharmaceutical** means any dosage form containing no viable microorganisms, including but not limited to parenterals and ophthalmics.

8.40.703 Deleted

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8.40.705 Deleted

8.40.703 (new) **Licensing**. All institutional pharmacies shall register annually with the Board of Pharmacy on a form or an electronic representation of a form provided by the board. Institutional pharmacies providing outpatient pharmacy services shall register the outpatient pharmacy separately.

8.40.704 (new) **Personnel**

(a) Each Institutional Pharmacy shall be directed by a pharmacist-in-charge, who is licensed to engage in the practice of pharmacy in the State of Montana and who is responsible for the storage, compounding, repackaging, dispensing and distribution of drugs within the facility. Depending upon the needs of the facility pharmacy services may be provided on a full or part-time basis, with emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

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(b) Registered pharmacy technicians or technicians in training may be utilized pursuant to the written policies and procedures of the institutional pharmacy. Exemptions to established ratios as defined in 8.40.1308 may be granted with board approval.

8.40.705 (new) **Absence of Pharmacist.**

(a) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. A pharmacist must be available by phone for consultation during all absences.

(b) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinet(s), determine who may have access, and shall ensure that:
  (1) all drugs are properly labeled;
  (2) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;
  (3) whenever access to the cabinet occurs, a copy of written practitioner's orders with date and time, identification of patient and room number, if applicable, name and quantity of drug removed, and signature of the person removing the drug(s) must be provided on a suitable form;
  (4) a complete verification audit of all orders and activity concerning the night cabinet is conducted by the pharmacist-in-charge or his or her designee within 24 hours; and
  (5) written policies and procedures are established to implement the requirements of this section.

(c) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by a supervisory registered nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility. Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number if applicable, name, strength and quantity of drug, date, time, and signature of nurse. The form shall be sequestered in the pharmacy with the container from which the drug was removed, and a copy of the original drug order. A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. A patient profile containing the patient's name, location, allergies, current medication regimen and relevant laboratory values shall be prospectively reviewed.

(d) In an institutional facility that does not have an in-house pharmacy, drugs may be provided for use by authorized personnel through emergency kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such kits must meet the following requirements:
  (1) A registered pharmacist shall prepare and seal all emergency drug kits;
  (2) The supplying pharmacist and the staff physician or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in each emergency kit;
  (3) Emergency kits shall be locked and stored in secure areas to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein;
  (4) All drugs shall be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient.
  (5) The exterior of each emergency kit shall be clearly labeled to indicate its use and expiration date of its contents, the name, address and telephone number of the supplying pharmacist, and a statement indicating that the kit is to be used in emergency situations only pursuant to a valid drug order;
  (6) Drugs shall be removed from emergency kits only by the supplying pharmacist or by authorized personnel pursuant to a valid drug order;
  (7) The supplying pharmacist shall be notified of any entry into the kit within 24 hours of its occurrence, and shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients;
  (8) The expiration date of an emergency kit shall be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug, and;
  (9) The supplying pharmacist shall, in conjunction with the appropriate institutional committee, be responsible for development of policies and procedures for safe and appropriate use and maintenance of emergency drug kits.

8.40.706 (class IV, family planning) remains unchanged

8.40.707 Drug Distribution and Control.

(a) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which prospective drug review will be accomplished. A current copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) Automated dispensing devices shall be stocked with drugs only by or under the supervision of a registered pharmacist. At the time of removal of any drug, it shall automatically make an electronic record indicating the date of removal, name, strength and quantity of drug removed, name of the patient for whom the drug was ordered, and the name or other identification of the person removing the drug. These records shall be maintained for a period of two years.

(c) Drugs or herbal/alternative food supplement products brought into an institutional facility by a patient shall not be administered unless they can be identified and their quality assured by a pharmacist, and their use has been authorized by the attending physician. If such drugs are not to be administered, the pharmacist-in-charge shall develop policies and procedures for storing them for return to the patient upon discharge or transferring them to an adult member of the patient's immediate family.

(d) Investigational drugs shall be stored in and dispensed from the pharmacy only pursuant to written policies and procedures. Complete information regarding these drugs and their disposition shall be maintained in the pharmacy. The drug monograph and a signed patient consent form shall be obtained and made available in accordance with federal guidelines.

8.40.708 Responsibility

The pharmacy director/pharmacist-in-charge shall provide for applicable policies and procedures to ensure:

(a) Mechanisms for receiving and verifying drug orders from prescribers, and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;

(b) Procedures for filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;

(c) Establishment of a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the department of nursing will provide education and training

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of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;

(d) Establishment of appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;

(e) Establishment of a mechanism by which changes in a patient's medication regimen are conveyed to that patient's home pharmacy;

(f) Maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;

(g) Pharmacy participation in formulary development;

(h) Participation in drug utilization review and monitoring of adverse drug reactions and development of procedures to avoid problems identified;

(i) Evaluation of reported medication errors and development of procedures to prevent these;

(j) Proper acquisition and secure, temperature-controlled storage of all prescription drugs;

(k) Quality control of sterile and non-sterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;

(l) Pharmacy safety and security;

(m) Utilization of registered technicians or technicians in training;

(n) Accurate distribution systems and secure, temperature-controlled storage of pharmaceutical products throughout the institution;

(o) Unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;

(p) Effective procedures regarding the use, security and accountability of controlled substances;

(q) Staff development and competency evaluation;

(r) Maintenance of all required records;

(s) All other requirements of the Montana Board of Pharmacy

8.40.709 Sterile products

(a) Policies and procedures shall be prepared for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceutical products. They shall include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies and procedures shall be current and available for inspection by a designee of the Board of Pharmacy.

(b) An institutional pharmacy compounding sterile products shall have an area restricted to entry by authorized personnel. This area must be designed to avoid unnecessary traffic and airflow disturbances.

(c) An institutional pharmacy compounding sterile products shall utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity.

(d) Cytotoxic drugs must be prepared in a vertical flow class II biological safety cabinet. Non-cytotoxic sterile pharmaceuticals should not be compounded in this cabinet.

(1) Protective apparel including non-vinyl gloves, gowns and masks shall be available, and gloves must be worn at all times.

(2) Appropriate containment techniques shall be used in addition to aseptic techniques required for sterile product preparation.

(3) Prepared doses of cytotoxic drugs must be clearly identified, labeled with proper precautions and dispensed in a manner to minimize risk of cytotoxic spills.

(4) Disposal of cytotoxic waste shall comply with all applicable local, state and federal laws.

(5) Written procedures for handling cytotoxic spills must be included in the policies and procedures manual.

(e) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.

(f) All aseptic environmental control devices shall be certified by an independent contractor for operational efficiency at least every 12 months or when relocated, according to Federal Standard 209E. Pre-filters must be inspected periodically and replaced if needed.

(1) Inspection and replacement dates must be documented and maintained for a period of at least two years.

(g) Documented records of ongoing quality assurance programs, justification of expiration dates chosen, and employee training records and technique audits shall be available for inspection by the Board of Pharmacy.

Continuing Medical Education (CME) credit

8.40.1003 approved programs (1) Continuing education programs sponsored by providers that are approved by the American Council on Pharmaceutical Education (ACPE) ***or programs that have been approved for Continuing Medical Education (CME) by a state board of Medical Examiners or its equivalent or the American Board of Medical Specialties*** will automatically qualify for continuing education credit.

Pharmacy Security Requirements (addition)

8.40.1213 (4) ***The registrant shall notify law enforcement officials of any theft or loss of any dangerous drug promptly upon discovery of such theft or loss and forward a copy of that agency's report to the board within 30 days.***

Preceptor Requirements (addition)

8.40.904 (c) ~~be engaged in full time practice;~~ ***be engaged in active practice while acting as preceptor;***

Technician Ratio (addition)

8.40.1308 (5) ***If a pharmacy desires more than one technician to work under the supervision, direction and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist in charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to, the following:***

1) design and equipment;

2) information systems;

3) work flow;

4) quality assurance procedures.

(a) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians.

(b) No pharmacy shall modify a board approved pharmacy service plan without the prior written approval of the board.

Acceptance of FPGEE for Foreign Graduates

8.40.403 ***(3) An interview by the board of pharmacy or its designee, the Test of English as a Foreign Language, Test of Spoken English and the Foreign Pharmacy Graduate Equivalency Examination™ provided by the National Association of Boards of Pharmacy® will be required for pharmacy graduates from outside the 50 states, the District of Columbia or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American Pharmacist Licensure Examination. A scaled score of 75 or greater will be the passing score for this examination. A candidate who does not attain this score may retake the examination after a 91 day waiting period.***

8.40.404 ***(22) Foreign Pharmacy Graduate Equivalency Examination™ (FPGEE®) initial fee $700 (23) Foreign Pharmacy Graduate***

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Equivalency Examination™ (FPGEE®) re-examination fee after failure $500

Medication Return from Long Term Care Facilities

Definitions: "Long term care facility" has the meaning provided in 50-5-101

"Provisional pharmacy" means a pharmacy licensed by the Montana board of pharmacy and includes but is not limited to federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

"Qualified patients" means patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs.

(1) In facilities licensed by the Montana Department of Health and Human Services where United States Pharmacopeia storage requirements can be assured, unit-dosed legend drugs, with the exception of controlled substances, no longer needed by the patient for whom they were prescribed, may be transferred to a provisional permitted pharmacy for relabeling and dispensing free of charge to patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs. Prescription medications may only be dispensed pursuant to a valid prescription order. A usual and customary dispensing fee may be charged at the pharmacist's discretion.

(2) The pharmacist in charge of the provisional permitted pharmacy shall be responsible for determining the suitability of the legend drug for use. Medications must be unopened in sealed, unaltered unit dose containers that meet USP standards for light, moisture and air permeation. No product in which drug integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.

(3) A re-dispensed prescription medication shall be assigned the expiration date stated on the unit dose packaging. Medications packaged in unit dose form within a pharmacy shall be given an expiration date of one year or actual date of expiration of the medication, whichever comes first and shall not be repackaged.

(4) No medication shall be redistributed more than once.

(5) Only authorized personnel shall carry out the physical transfer of medication in either facility, pursuant to established policies and procedures.

(6) The patient's name and other identifying marks shall be obliterated from packaging prior to transfer. The drug name, strength, lot number and expiration date shall remain clearly visible on the packaging.

(7) An inventory list of drugs transferred, including expiration dates, shall accompany the drugs, and shall be maintained in the provisional permitted pharmacy for a period of two years.

(8) Policies and procedures to document safe storage and transfer of unneeded medications shall be written and adhered to by the facilities involved, and shall be available for inspection by an authorized representative of the Montana Board of Pharmacy or Public Health and Human Services.

Pharmacist Meal/Rest Breaks – see April 2002 Newsletter

Patient Counseling: Room for Improvement

A recent small study by North Dakota State University comparing patient consultation by **pharmacists** versus **health food store employees** showed that there was little difference in the quality of information received by the patient with regard to over-the-counter medications for relief of arthritis. If that does not make you reach for the Pepcid AC, I do not know what will. Good patient counseling has the potential to be one of the most interesting and rewarding aspects of pharmacy practice. Insufficient, ineffective counseling has the potential to cause harm to your patients and, in turn, cause harm to you and your practice. Most pharmacists take their counseling responsibilities seriously. If you are not included in that select group of professionals, now would be a good time to start. Effective July 1, 2003, all Montana pharmacies are required to have a private counseling area. The area does not have to be a separate room, but must offer **visual** and **auditory** privacy. It can simply be a soundproof wall or a few sheets of plywood out of the traffic area. It does not take a degree in engineering, only the desire to provide optimal patient counseling. The implementing rule was passed two years ago, and the clock is running. The Board encourages you to look critically at your counseling procedures and your counseling area for the safety of your patients as well as your practice.

The *Montana Board of Pharmacy News* is published by the Montana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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